DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-22-22GA; Docket No. CDC-2022-0076]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Expanding PrEP in Communities of Color (EPICC). The proposed study is designed to deliver training to health providers on implementation of evidence-based tools to enhance the providers' ability to engage in PrEP screening, counseling, initiation and to provide support for adherence and persistence, and to test the effectiveness of the EPICC intervention.

DATES: CDC must receive written comments on or before [INSERT DATE 60 DAYS AFTER PUBLICATION DATE IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments, identified by Docket No. CDC-2022-0076 by either of the following methods:

- Federal eRulemaking Portal: www.regulations.gov. Follow the instructions for submitting comments.
- Mail: Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to www.regulations.gov.

Please note: Submit all comments through the Federal eRulemaking portal (www.regulations.gov) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, MS H21-8, Atlanta, Georgia 30329; Telephone: 404-639-7118; E-mail: omb@cdc.gov.

SUPPLEMENTARY INFORMATION:

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. In addition, the PRA also requires federal agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each new proposed collection, each

proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
3. Enhance the quality, utility, and clarity of the information to be collected;
4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses; and
5. Assess information collection costs.

Proposed Project

Expanding PrEP in Communities of Color (EPICC) – New - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention (NCHHSTP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP) is requesting approval for 36 months of a data collection titled Expanding PrEP in Communities of Color (EPICC). The purpose of this study is to implement and evaluate the effectiveness of a clinic-based intervention that utilizes evidence-based education and support tools to: 1. increase provider knowledge of and comfort with preexposure prophylaxis (PrEP) modalities in clinical practice, and 2. improve PrEP adherence among young men who have sex with men (YMSM).

This study has two aims: In Aim 1 the study team will deliver training to health providers that will focus on implementation of evidence-based tools to enhance the providers' ability to engage in PrEP screening, counseling, initiation and to provide support for adherence and persistence. For Aim 2a, the study will initiate an effectiveness-implementation trial with 400 YMSM to test the effectiveness of the EPICC+ intervention package in increasing PrEP adherence and persistence among YMSM. The intervention will also utilize a mobile app-based platform, HealthMPowerment (HMP) to support ongoing participant engagement and monitoring, as well as to provide additional adherence support. In Aim 2b the study team

will conduct focus groups with providers to gather feedback on overall perceptions of the barriers and facilitators to implementation of evidence-based tools (EBT) within their clinical site.

The information collected in this study will be used to: 1) describe real-world PrEP use including factors influencing selection and change of PrEP regimens; 2) understand and describe barriers and facilitators impacting the implementation of new PrEP modalities in clinical practice; 3) evaluate the feasibility and acceptability of the EPICC+ mobile app among YMSM on PrEP; and 4) evaluate the feasibility and acceptability of implementing a provider training.

This study will be carried out in 10 clinics located in Chicago, IL; New York City, NY; Philadelphia, PA; Charlotte, NC; Raleigh, NC; Tuscaloosa, AL; Montgomery, AL; Tampa, FL; Orlando, FL; and Houston, TX. Aim 1 will include 30 health care providers from the 10 clinic sites, all involved in the direct delivery of PrEP services. Providers may include but are not limited to medical doctors, nurses, adherence counselors, pharmacists, and social workers. Health providers will be recruited via staff emails.

Aim 2a participants will include 400 YMSM ages 18-39. Participants will identify as a cisgender male; report sex with a man in the past 12 months; have an active prescription for PrEP; receive care at one of the 10 participating study sites; provide a mailing address within the 50 states where packages

can be received; have daily smartphone access; and be fluent in written/spoken English or Spanish. We will use purposive sampling to ensure at least 60% patient sample is African American or Black or Hispanic/Latino/Latinx. Patient participants will be recruited to the study using a combination of approaches including social media, referral and in-person outreach.

Quantitative and qualitative assessments will be used to collect information from providers and YMSM participants. For the Aim 1 provider training, assessments will include pre, post, 3-month, and 6-month surveys to evaluate provider information retention. Providers will also be asked to complete a brief survey at baseline, 3- and 6-months to assess their new patient interaction skills. For Aim 2a, YMSM participants will be asked to complete a baseline assessment and quarterly assessments at 3-, 6-, 9-, 12-, 15-, and 18-months to assess PrEP adherence; PrEP knowledge, usage and choice; sexual risk behaviors; HIV status of partners; and substance use assessment. A subset of YMSM participants from Aim 2a will be asked to complete an exit interview that will focus on understanding factors that influenced participants' selection of PrEP regimens, changes and/or discontinuations, as well as perceptions of the counseling they received by providers at PrEP initiation and follow-up, receipt of tools or materials that influenced choice and feasibility/acceptability of the HMP app. We will also conduct focus groups with providers in Aim 2b to gather feedback

on overall perceptions of the barriers and facilitators to EBT implementation within their clinical site. The study will also collect data through from electronic health records; biological specimens collected at quarterly intervals; and a clinic assessment tool delivered every six months.

For the Aim 1 provider training, we estimate the collection of contact information will take five minutes. Pre-training, baseline and follow up surveys at 3- and 6-months will take approximately 15 minutes each to complete. Patient interaction assessments delivered at baseline, 3-, and 6-months will take approximately 15 minutes each to complete. For Aim 2a, the effectiveness-implementation trail, it is expected that 50% of YMSM screened will meet study eligibility. The initial screening will take five minutes to complete and the collection of contact information to take five minutes. The baseline assessment will take approximately 45 minutes to complete. The follow-up assessments will take 45 minutes to complete and will be administered quarterly for a total of six times during the 18-month follow up period. Study staff will assist participants to setup the HMP app, a process that will take 30 minutes. The patient exit interview takes approximately 60 minutes to complete and will be delivered one time to a subset of 48 YMSM participants. For the Aim 2b provider focus groups, we estimate it will take approximately five minutes to collect contact information and another five minutes to conduct the pre-focus

group survey. Providers will attend one focus group that is expected to take 120 minutes to complete.

Total study enrollment for Aim 1 is 30, over the three-year study period the estimated annual enrollment is 10. Total enrollment for aim 2a is 400, over the three-year study period the estimated annual enrollment is 134. For the Aim 2a exit interview, 45 will participate for an annual enrollment of 15. For Aim 2b, total study enrollment is 48 and the estimated annual enrollment is 16. Additionally, a clinic staff member at each of the ten participating clinic sites will complete a clinic assessment form every six months throughout the study period.

The total number of burden hours is 2,055 across 36 months of data collection. The total estimated annualized burden hours are 685. There are no costs to the participant other than their time to participate.

Estimated Annualized Burden Hours

Type of Respondent	Form Name	Number of Respondents	Number of Responses per Respondent	Average Burden per Response (in hr)	Total Burden (in hr)
General Public - Adults	Aim 1 Provider Contact Information	10	1	5/60	1

General Public - Adults	Aim 1 Provider Training Survey	10	4	15/60	10
General Public - Adults	Aim 1 Patient Interaction Assessment	10	3	15/60	8
General Public - Adults	Aim 2a Participant Eligibility Screener	268	1	5/60	23
General Public - Adults	Aim 2a Participant Contact Information	134	1	5/60	12
General Public - Adults	Aim 2a Baseline Assessment	134	1	45/60	101
General Public - Adults	Aim 2a Quarterly Assessments	134	4	45/60	402
General Public - Adults	Aim 2a HMP App Setup	134	1	30/60	67
General Public - Adults	Aim 2a Exit Interview	15	1	1	15
General Public - Adults	Aim 2b Provider Focus Group Contact Information	16	1	5/60	2

General Public - Adults	Aim 2b Provider Focus Group Survey	16	1	5/60	2
General Public - Adults	Aim 2b Provider Focus Group Guide	16	1	2	32
General Public - Adults	Clinic Assessment	10	2	30/60	10
Total					685

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